Notice of Allowability	Application No.	Applicant(s)	
	10/693,377	BOONE ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *6/16/2010; 3/23/2010*.

2. ☒ The allowed claim(s) is/are *1,2,8-10,12,17,20 and 30-32*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/23/2010
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *attached herewith* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Ashley N. Sturgeon, Reg.64,819 And Ms. Jean M. Dickman, Reg. 48,538 on June 16, 2010 and June 14, 2010, respectively

The application has been amended as follows:

1. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

determining that the sample contains an elevated level of lactoferrin <u>compared to a lactoferrin level in a healthy control</u>;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil cytoplasmic antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

30. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

contacting the diluted sample with immobilized polyclonal antibodies to endogenous lactoferrin to create a first treated sample;

contacting said first treated sample with enzyme-linked polyclonal antibodies such that the enzyme-linked polyclonal antibodies are allowed to bind to captured endogenous lactoferrin creating an enzyme-linked antibody bound sample;

adding a substrate to the enzyme-linked antibody bound sample to create a readable sample;

determining the optical density of said readable sample at 450 nm;

determining that the sample contains an elevated level of lactoferrin compared to a lactoferrin level in a healthy control;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil cytoplasmic antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

31. (Previously Presented) The method of claim 30, further comprising:

contacting the sample with antigens of *Saccharomyces cerevisiae* to create a second treated sample;

contacting the second treated sample with polyvalent antibodies to human immunoglobulin conjugated to an enzyme such that the polyvalent antibodies are allowed to bind to capture anti-*Saccharomyces cerevisiae* antibodies creating an enzyme-linked antibody bound sample;

adding a substrate to the enzyme-linked antibody bound sample to create a readable sample; and

determining the optical density of the readable sample.

32. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

contacting the sample with neutrophil cytoplasmic antigens to create a treated sample;

contacting the treated sample with polyvalent antibodies to human immunoglobulin such that the enzyme-linked polyvalent antibodies are allowed to bind to capture anti-neutrophil cytoplasmic antibodies creating an enzyme-linked antibody bound sample;

adding an enzyme substrate to the enzyme-linked antibody bound sample to create a readable sample;

determining an optical density of the readable sample at 450 nm;

determining that the sample contains an elevated level of lactoferrin compared to a lactoferrin level in a healthy control;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

/Ginny Portner/
Examiner, Art Unit 1645
June 16, 2010